FORM PTO-1390 REV. 5-93	US DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTORNEYS DOCKET NUMBER P00,1120
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371		U.S.APPLICATION NO. (if known, see 37 CFR 1.5) 09/581587

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/DE98/03620	**09 December 1998**	**19 December 1997**

TITLE OF INVENTION

DEVICE FOR GIVING A TRANSFUSION AND/OR PERFUSION TO A PATIENT

APPLICANT(S) FOR DO/EO/US

KLAUS ABRAHAM-FUCHS, THOMAS BIRKHOELZER and VOLKER SCHMIDT

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay.
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of International Application as filed (35 U.S.C. 371(c)(2)) - drawings attached.
   a. ☒ is transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☐ has been transmitted by the International Bureau.
   c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US)
6. ☒ A translation of the International Application into English (35 U.S.C. 371(c)(2) - drawings attached.
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. §371(c)(3))
   a. ☐ re transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☐ have been transmitted by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☐ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). Unexecuted
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern other document(s) or information included:

11. ☒ An Information Disclosure Statement under 37 C.F.R. 1.97 and 1.98; **(PTO 1449, Prior Art, Search Report)**.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 C.F.R. 3.28 and 3.31 is included.
13. ☒ A **FIRST** preliminary amendment.
    ☐ A SECOND or SUBSEQUENT preliminary amendment.
14. ☐ A substitute specification.
15. ☐ A change of power of attorney and/or address letter.
16. ☒ Other items or information:
    a. ☒ Submission of Drawings -
    B. ☒ Express Mail Label EL 568800039US
    Request for Approval of Drawing changes
    Information Disclosure Statement

U.S.APPLICATION NO. (if known, see 37 C.F.R. 1.5)	INTERNATIONAL APPLICATION NO.	ATTORNEY'S DOCKET NUMBER
09/581587	PCT/DE98/03620	P00,1120

17. ☒ The following fees are submitted:	CALCULATIONS	PTO USE ONLY
BASIC NATIONAL FEE (37 C.F.R. 1.492(a)(1)-(5): Search Report has been prepared by the EPO or JPO . . . . . $840.00 International preliminary examination fee paid to USPTO (37 C.F.R. 1.482)$670.00 No international preliminary examination fee paid to USPTO (37 C.F.R. 1.482) but international search fee paid to USPTO (37 C.F.R. 1.445(a)(2) . $760.00 Neither international preliminary examination fee (37 C.F.R. 1.482) nor international search fee (37 C.F.R. 1.445(a)(2) paid to USPTO . . . . $970.00 International preliminary examination fee paid to USPTO (37 C.F.R. 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4) . . . . . $ 96.00		
ENTER APPROPRIATE BASIC FEE AMOUNT =	$ 840.00	
Surcharge of $130.00 for furnishing the oath or declaration later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 C.F.R. 1.492(e)).	$	

Claims	Number Filed		Number Extra	Rate		
Total Claims	18	- 20 =		X $18.00	$ 00	
Independent Claims	01	- 3 =		X $ 78.00	$ 00	
Multiple Dependent Claims				$260.00 +		
TOTAL OF ABOVE CALCULATIONS =					$840.00	
Reduction by ½ for filing by small entity, if applicable. Verified Small Entity statement must also be filed. (Note 37 C.F.R. 1.9, 1.27, 1.28)					$	
SUBTOTAL =					$ 840.00	
Processing fee of $130.00 for furnishing the English translation later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(f)). +					$	
TOTAL NATIONAL FEE =					$ 840.00	
Fee for recording the enclosed assignment (37 C.F.R. 1.21(h). The assignment must be accompanied by an appropriate cover sheet (37 C.F.R. 3.28, 3.31). $40.00 per property +						
TOTAL FEES ENCLOSED =					$ 840.00	
					Amount to be refunded	$
					charged	$

a. ☒ A check in the amount of $840.00 to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account No. _____ in the amount of $_____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 08-2290. A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 C.F.R. 1.494 or 1.495 has not been met, a petition to revive (37 C.F.R. 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

Hill & Simpson
A Professional Corporation
85th Floor Sears Tower
Chicago, Illinois 60606

Steven H. Noll
SIGNATURE

Steven H. Noll
NAME

28,982 (Registration No.)

IN THE UNITED STATES DESIGNATED OFFICE

OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

UNDER THE PATENT COOPERATION TREATY-CHAPTER II

AMENDMENT "A" PRIOR TO ACTION

APPLICANTS: Abraham-Fuchs et al.

ATTORNEY DOCKET NO. P00,1120

INTERNATIONAL APPLICATION NO: PCT/DE98/03620

INTERNATIONAL FILING DATE: December 9, 1998

INVENTION: "DEVICE FOR GIVING A TRANSFUSION AND/OR PERFUSION TO A PATIENT"

Assistant Commissioner for Patents

Washington, D.C. 20231

Sir:

Applicants herewith amend the above-referenced PCT application as follows, and request entry of the Amendment prior to examination in the United States National Examination Phase.

IN THE TITLE:

Please cancel the present title and substitute the following title therefor:

--DEVICE FOR ADMINISTERING A FLUID TO A PATIENT BY INFUSION AND/OR PERFUSION--.

IN THE SPECIFICATION:

On page 1, cancel the material above line 6 and substitute the following therefor:

--TITLE

"DEVICE FOR ADMINISTERING A FLUID TO A PATIENT BY INFUSION AND/OR PERFUSION"

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention is directed to a device for administering a fluid to a patient, such as by infusion and/or perfusion.

Description of the Prior Art--;

cancel line 7 and substitute the following therefor:

One of the tasks of intensive care medicine is to balance disorders relating to the fluid, electrolyte--;

in line 8, cancel "parenterally nourish" and substitute --provide supervised nourishment to-- therefor;

in line 14, cancel "metabolism, whereby these" and substitute --metabolism. These-- therefor;

in line 20, cancel "appertaining" and substitute --of-- therefor; and

in line 29, cancel "whereby the-- and substitute --with-- therefor.

On page 2, in line 1, cancel "sodium-, potassium-" and substitute --sodium, potassium-- therefor, cancel "are" and substitute --being-- therefor, and cancel "here";

in line 7, cancel "parenteral" and substitute --supervised-- therefor;

in line 12, insert --manually-- preceding "prescribed", and cancel "by hand";

in line 13, cancel "potentially", and after "modified" (and before the period) insert --as needed--;

in line 15, cancel "specification" and substitute --discussion-- therefor;

in line 16, cancel "insecure" and substitute --imprecise-- therefor, and cancel "nutriments [sic]", and cancel "enable" and substitute --result in-- therefor;

in line 19, cancel ", respectively," (both occurrences);

in line 20, cancel ", respectively,"; and

in line 23, cancel "DE-" and substitute --German-- therefor.

On substitute page 3, in line 1 cancel "DE" and substitute --German OS-- therefor, and cancel "A1";

cancel lines 5, 6 and 7;

in line 9, cancel "EP" and substitute --European Application-- therefor, and cancel "A2";

in line 14, cancel "US 4 392 849 relates to" and substitute --United States Patent No. 4,392,849 discloses-- therefor, and preceding "WO" insert --PCT Application--; and

cancel lines 18-28 and substitute the following therefor:

--**SUMMARY OF THE INVENTION**

It is an object of the present invention to provide a device for administering fluid to a patient, such as by infusion and/or perfusion, which operates in a manner that is closely adapted to the actual patient conditions, even as such conditions change over time.

The above object is achieved in accordance with the principles of the present invention in a device for administering a fluid to a patient by infusion and/or perfusion, wherein one or more sensors is provided for measuring real values, respectively, of one or more patient-specific parameters, and wherein the sensor or sensors are connected to a control unit. An infusion device and/or a perfusion device communicates with the control unit and administers the fluid, such as an infusion solution or a perfusion solution, dependent on signals from the control unit. The control unit controls the infusion amount and/or perfusion amount that is to be supplied by the device dependent on the acquired real values from the sensors.--.

On substitute page 3a, in line 1, cancel "particulary" and substitute --particularly-- therefor;

in line 5, cancel "means" and substitute --unit-- therefor; and

in line 6, cancel "means" and substitute --unit-- therefor.

On page 4, in line 4, cancel "it has", cancel "been", and cancel ", respectively,";

in line 5, cancel ", however, partially";

in line 7, after "are" insert --able to be--;

in line 8, cancel "means" and substitute --unit includes-- therefor;

in line 9, cancel "comprises [sic]";

in line 10, cancel "it" and substitute --this processing-- therefor, cancel "These" and substitute --Such an-- therefor, and cancel "[sic]";

in line 11, cancel "whereby" and substitute --wherein-- therefor;

in line 12, cancel "has [sic]" and substitute --have-- therefor;

in line 13, cancel "therefore" and substitute --i.e., they are-- therefor;

in line 16, cancel "is" and substitute --can be-- therefor;

in line 17, cancel "certainly provided", cancel "a corresponding regulation-" and substitute --regulation-- therefor, and cancel "on" and substitute --in-- therefor;

in line 18, cancel "the side of", and cancel "means" and substitute --unit-- therefor;

in line 20, cancel "purposes of";

in line 21, cancel "controlling, and which" and substitute --controlling. These relations and information-- therefor, and cancel "previously" and substitute --conventionally-- therefor;

in line 22, insert --the physician's-- preceding "own";

in line 22, cancel "was certainly given hereby" and substitute --existed-- therefor;

in line 2, after "system" (and before the period) insert --in accordance with the invention--;

in line 26, cancel "means" and substitute --unit-- therefor, and cancel "allow [sic] a critically" and substitute --allows a significantly-- therefor; and

in line 28, cancel ", respectively,".

On page 5, in line 1, cancel "it has", cancel "been", cancel "the" preceding "intensive", and insert --care-- after "intensive";

in line 4, cancel "per se", cancel "DE" and substitute --German PS-- therefor, and cancel "C2";

in line 5, cancel "plurality" and substitute --number-- therefor;

in line 6, cancel "means" and substitute --unit-- therefor;

in line 9, cancel "the greatest" and substitute --a large-- therefor;

in line 10, cancel "thereby comprise" and substitute --include-- therefor;

in line 11, cancel "outputted upon" and substitute --dispensed under the-- therefor;

in line 12, cancel "means" and substitute --unit-- therefor, and cancel "that";

in line 14, cancel "plurality" and substitute --number-- therefor;

in line 15, cancel "means" and substitute --unit-- therefor;

in line 18, cancel "require" and substitute --are required-- therefor;

in line 19, insert --inventive-- preceding "device";

in line 20, cancel "it can be provided, according to an advantageous";

in line 21, cancel "further development of the inventive idea that" and substitute --in a further embodiment of the invention-- therefor, and cancel "means comprises" and substitute --unit has-- therefor;

in line 22, cancel "means" and substitute --interfaces-- therefor;

in line 23, cancel "outputted" and substitute --dispensed-- therefor;

in line 24, cancel ""Deficient supply,";

in line 25, cancel "balancing supply and excess supply" means a corresponding" and substitute --In the context of the-- therefor;

in line 26, cancel "as much as a hypo-caloric supply, normo" and substitute --a "deficient supply" means that a hypo-caloric situation exists, a "balanced supply" means that a normal caloric situation should be maintained, and an "excess supply" means that a hyper caloric situation exists, and the administered fluid should be adjusted according to the respective situation so as to appropriately influence the-- therefor;

cancel line 27; and

in line 28, cancel "when" and substitute --for-- therefor, cancel "means" and substitute --unit-- therefor, and cancel "is" and substitute --to be-- therefor.

On page 6, in line 2, cancel "at the side of" and substitute --by-- therefor, cancel "means regarding this" and substitute --unit-- therefor;

in line 3, cancel ", respectively,";

in line 6, cancel "the case of a" and substitute --certain cases,-- therefor, and cancel "being able to" and substitute --can-- therefor;

in line 7, cancel "solutions, as this, for" and substitute --solutions.-- therefor;

in line 8, cancel "example, is valid for the caloric metabolism, whic [sic]" and substitute --Caloric metabolism, for example, is such a case, which-- therefor;

in line 9, cancel "with respect to";

cancel line 10 and substitute the following therefor: "in appropriate amounts and combinations.--

in line 11, cancel "it can be further provided that" and substitute --For these types of cases, in further embodiment of the invention-- therefor, cancel "means" after "control" and substitute --unit-- therefor, and cancel "sensor means" and substitute --sensors connected thereto-- therefor;

in line 12, cancel "possibly" and substitute --as well as, if needed,-- therefor, and cancel "means" and substitute --interfaces-- therefor;

in line 14, cancel "means" and substitute --interfaces-- therefor;

in line 15, cancel "this can be such that he" and substitute --the physician-- therefor;

in line 17, cancel "Here, the control means" and substitute --In this embodiment as well, the control unit-- therefor, and cancel "also";

in line 22, cancel "when one or more sensor means can" and substitute --for the sensor or sensors to-- therefor;

in line 24, cancel "one or more sensor means" and substitute --sensor or sensors-- therefor;

in line 26, cancel "means" and substitute --unit-- therefor;

in line 27, cancel "the" preceding "calibrating" and substitute --any-- therefor;

in line 28, cancel "is potentially" and substitute --may be-- therefor; and

in line 29, cancel "when" and substitute --for-- therefor.

On page 7, in line 1, cancel "is" and substitute --to be-- therefor, and cancel "means" after "control" and substitute --unit-- therefor;

in line 2, cancel "value, which" and substitute --value. The-- therefor;

in line 3, cancel "alarm" and substitute --alert-- therefor, and cancel "in the case of a found" and substitute --if a-- therefor, and after "complication" (and before the comma) insert --is detected--;

in line 4, cancel "deposited" and substitute --stored-- therefor, and cancel "means" and substitute --unit-- therefor;

in line 14, cancel "with regard to an optimally" and substitute --within a wide range of usage-- therefor;

in line 15, cancel "broad utilizations spectrum", cancel "it", cancel "requested", and cancel "the" after "in";

in line 16, after "intensive" insert --care--;

in line 18, cancel "According to a" and substitute --In a further-- therefor;

in line 20, cancel "are [sic]", and cancel "sensor means" and substitute --sensors-- therefor;

in line 21, cancel "means of", after "control" cancel "means" and substitute --unit- - therefor, and cancel "part";

in line 22, cancel "patial [sic]" and substitute --partial-- therefor; and

in line 27, after "creatinine" insert --level--, and insert --and-- preceding "body".

On page 8, in line 1, cancel "characterized in that it is";

in line 2, cancel "plurality" and substitute --number-- therefor;

in line 3, cancel "in that" and substitute --with-- therefor;

in line 4, cancel "means";

in line 8, cancel "can be hang up" and substitute --from respective suspended bags- - therefor;

in line 9, cancel "outputted" and substitute --dispensed-- therefor;

in line 11, after "allocated" insert --respectively--, and after "or" cancel ", respectively,";

in line 12, after "device" insert --can be provided--, and cancel "purposes of";

in line 14, cancel "line, whereby this" and substitute --line. This-- therefor;

in line 15, cancel "in" and substitute --to-- therefor;

in line 16, cancel "given" and substitute --introduced-- therefor;

cancel lines 17 - 21 and substitute the following therefor:

--**DESCRIPTION OF THE DRAWING**

The single figure is a schematic block diagram of a device for administering a fluid by infusion and/or perfusion to a patient, constructed and operating in accordance with the principles of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The figure schematically illustrates an inventive device connected to a patient 1--;

in line 22, cancel "shown", and cancel "an" and substitute --a fluid by-- therefor;

in line 23, cancel "means" (both occurrences), and cancel "tubus" and substitute --breathing tube-- therefor, and cancel "serves" and substitute --monitors-- therefor;

in line 24, cancel "sensory mechanism" and substitute --parameters-- therefor;

in line 25, cancel "means of", and cancel "means" after "sensor";

in line 28, cancel "given" and substitute --supplied-- therefor, and cancel "means": and substitute --unit-- therefor, and cancel "permanent" and substitute --or venous long-term-- therefor; and

in line 29, cancel "or a venous permanent catheter 7", and cancel "sensor means" and substitute --sensors-- therefor.

On page 9, in line 1, cancel "the" preceding "blood" and substitute --monitoring-- therefor, cancel "sensory mechanism" and substitute --parameters-- therefor, and cancel "1, which" and substitute --1. The-- therefor;

in line 2, cancel "means" after "sensor", cancel "are" and substitute --is-- therefor, and cancel "means" after "control" and substitute --unit-- therefor;

in line 4, cancel "[...] and substitute --or-- therefor, and cancel "and" and substitute --or-- therefor;

in line 5, cancel "potentially" and substitute --possibly-- therefor;

in line 6, cancel "sensor means" and substitute --sensors-- therefor;

in line 7, cancel "potentially" and substitute --possibly-- therefor;

in line 8, cancel "Real" and substitute --Again, real-time-- therefor, cancel "given" and substitute --supplied-- therefor, cancel "means" and substitute --unit-- therefor, and cancel "also";

in line 9, cancel "here";

cancel lines 11 and 12 and substitute the following therefor:

--The figure shows only an exemplary embodiment, and does not represent a limitation as to the type or number of sensors which can be employed.--;

in line 13, cancel "hereby not given.";

in line 14, cancel "as long as these are" and substitute --to the extent-- therefor;

in line 16, cancel "the load of" and substitute --distress to-- therefor;

in line 18, cancel "mostly" and substitute --usually-- therefor;

in line 20, cancel "sensor means" and substitute --sensors-- therefor;

in line 21, cancel "continuous" and substitute --repeated-- therefor;

in line 22, cancel "sensor means can" and substitute --sensors should-- therefor;

in line 23, cancel "such that is";

in line 24, cancel "means" and substitute --unit 5-- therefor;

in line 26, cancel "means" and substitute --unit-- therefor, and cancel "an infusion" and substitute --a fluid administration-- therefor;

in line 27, inert --which can be an infusion-- preceding "and/or", and cancel "11" after "perfusion device", and cancel "comprises" and substitute --has-- therefor;

in line 28, cancel "plurality" and substitute --number-- therefor; and

in line 29, cancel "13 a, b, c, d, e, whereby merely" and substitute --13a through 13e. Only-- therefor.

On page 10, in line 1, cancel "13a-e" and substitute --13a through 13e-- therefor;

in line 2, cancel "13a-e" and substitute --13a through 13e-- therefor;

in line 5, cancel "means" after "control" and substitute --unit-- therefor, and cancel "in its operation. This means" and substitute --so-- therefor;

in line 6, cancel "solution 13 a-e to be outputted" and substitute --solutions 13a through 13e to be dispensed-- therefor, and cancel "hereover" and substitute --by the control unit 5-- therefor;

in line 7, cancel "real" and substitute --real-time-- therefor, and cancel "means 5 due to the sensory mechanism" and substitute --unit 5 from the sensors 3 and 8-- therefor;

in line 8, cancel "be", and cancel "reacted" and substitute --react-- therefor;

in line 12, cancel "outputted" and substitute --dispensed-- therefor;

in line 14, cancel "given" and substitute --administered-- therefor;

in line 17, cancel "it has", and cancel "been";

in line 18, cancel "means" (both occurrences) and substitute --unit-- therefor (both occurrences);

in line 25, cancel "As it has already been described, the utilizable sensor means are not limited." and substitute --As noted above, various types of sensors can be employed.-- therefor; and

in line 27, cancel "these [sic]" and substitute --this-- therefor, and cancel "is" and substitute --are-- therefor.

On page 11, in line 1, cancel "is" and substitute --the glucose level and the potassium level are-- therefor, and cancel "range, whereby an" and substitute --range. An-- therefor;

in line 4, cancel "also";

in line 5, cancel "these [sic]" and substitute --this-- therefor;

in line 6, cancel "via the method the [sic]" and substitute --by-- therefor;

in line 9, cancel "here";

in line 11, cancel "controlling/regulating via" and substitute --control/regulation by-- therefor, cancel "means" and substitute --unit-- therefor, and cancel "Hereby, it can be chosen between a" and substitute --A selection can be made among-- therefor;

in line 13, cancel "whereby, appropriately, corresponding selection- and control means 5" and substitute --for which purpose an appropriate user interface-- therefor;

in line 14, cancel "Figure by means of the" and substitute --figure as-- therefor, and cancel "for this purpose";

in line 16, cancel "much" and substitute --many calories-- therefor, and cancel "he" and substitute --the patient-- therefor;

in line 18, after "automatically" insert --,-- and cancel "means" and substitute --unit 5-- therefor;

in line 20, cancel "means of the selection means" and substitute --the switches-- therefor;

in line 25, cancel "water-" and substitute --water-- therefor;

in line 27 cancel "means", (first occurrence) and after "control" cancel "means" and substitute --unit-- therefor; and

in line 29, cancel "here", and cancel "selection means" and substitute --switches-- therefor.

On page 12, in line 2, cancel "Appropriate one" and substitute --One-- therefor, and cancel "sensor means" and substitute --appropriate sensors--;

in line 3, cancel "[sic]";

in line 4, cancel "regarding its salt content" and substitute --, which in this case may be a saline solution,-- therefor, and cancel "[sic]", and cancel "means of ";

in line 5, cancel "means" and substitute --unit 5-- therefor, and cancel "also";

in line 8, cancel "Finally, an" and substitute --An-- therefor; and

below line 10, insert the following paragraph:

--Although modifications and changes may be suggested by those skilled in the art, it is the intention of the inventors to embody within the patent warranted hereon all changes and modifications as reasonably and properly come within the scope of their contribution to the art.--.

IN THE DRAWING:

Please amend the figure as shown on the drawing copy marked in red, attached to the Request for Approval of Drawing Changes filed simultaneously herewith.

IN THE CLAIMS:

On page 13, in line 1, cancel "Patent claims" and substitute:

--**WE CLAIM AS OUR INVENTION**-- therefor.

Please cancel claims 1-18 and substitute the following claims therefor:

19. A device for administering a fluid to a patient, comprising:

a sensor for emitting real-time values representing a physiological parameter of a patient;

a control unit supplied with said real-time values;

a fluid administration device selected from the group consisting of infusion devices and perfusion devices, in communication with said control unit, said fluid administration device containing a solution to be administered;

said control unit controlling said fluid administration device to dispenses said solution dependent on said real-time values; and

said control unit comprising an expert system which processes said real-time values as said real-time values are received from said sensor, to obtain a processes result, and said control unit continually updating control of said fluid administration device dependent on said processed result.

20. A device as claimed in claim 19 wherein said fluid administration device comprises a plurality of different solutions to be administered in respectively different dispensed amounts, and wherein said control unit controls administration of said different solutions in said different dispensed amounts dependent on said processing result.

21. A device as claimed in claim 20 wherein said fluid administration device further comprises a mixing device connected to all of said different solutions, said mixing device having a single output at which all of said different solutions are dispensed in said dispensed amount, controlled by said control unit.

22. A device as claim in claim 20 wherein said control unit comprises a manually actuatable selection element for selecting one of said solutions or a combination of said solutions to be dispensed to a patient.

23. A device as claim in claim 20 wherein said control unit automatically selects one of said solutions or a combination of said solutions to be dispensed by said fluid administration device.

24. A device as claim in claim 20 wherein said control unit comprises a user interface allowing manual adjustment of dispensing of said solution at least for adjusting a deficient supply, a balanced supply and an excess supply of said solution.

25. A device as claim in claim 19 wherein said control unit, based on said processed result, automatically controls said fluid administration device to change dispensing of said solution to adjust for a deficient supply, a balanced supply and an excess supply of said solution.

26. A device as claim in claim 19 further comprising a source of calibrating solution and rinsing and calibrating means connected to said sensor for rinsing said sensor and for calibrating said sensor with said calibrating solution.

27. A device as claim in claim 26 wherein said rinsing and calibrating means is connected to and controlled by said control unit.

28. A device as claim in claim 19 further comprising an alarm connected to said control unit, said alarm being triggered by said control unit dependent on at least one of said real-time values.

29. A device as claim in claim 19 wherein said sensor is a sensor selected from the group consisting of glucose sensors and potassium sensors, and wherein said control unit controls said fluid administration device to administer a fluid for influencing a metabolism selected from the group consisting of glucose metabolism and potassium metabolism.

30. A device as claim in claim 19 wherein said sensor comprises a sensor for sensing a parameter related to caloric metabolism, and wherein said control unit controls said fluid administration device to influence said caloric metabolism.

31. A device as claim in claim 19 wherein said sensor is a sensor selected from the group consisting of fluid sensors and electrolyte sensors, and wherein said control unit controls said fluid administration device to administer a fluid for influencing a metabolism selected from the group consisting of fluid metabolism and electrolyte metabolism.

32. A device as claim in claim 19 wherein said fluid administration device contains a plurality of fluids to be administered and a like plurality of separate lines for respectively supplying said different solutions to a central output line of said fluid

administration device, and at least one fluid flow modifier disposed in a path comprised of said separate lines and said central output line, controlled by said control unit.

33. A device as claim in claim 32 comprising a plurality of fluid flow modifiers respectively disposed in said separate lines and each connected to said control unit for modifying fluid flow in the respective separate lines.

34. A device as claim in claim 32 further comprising a mixing device connecting said separate lines to said central output lines.

35. A device as claim in claim 34 wherein said mixing device comprises a drop catcher to which said plurality of solutions are supplied via the respective separate lines drop-by-drop.

36. A device as claim in claim 19 wherein said sensor is a sensor selected from the group consisting of a sensor for measuring partial O_2 pressure in air inspired by said patient, a sensor for measuring partial O_2 pressure in air expired by said patient, a sensor for measuring partial CO_2 pressure in air expired by said patient a room temperature sensor, an air pressure sensor, a sensor for measuring a temperature of the patient, a sensor for measuring a blood potassium level of the patient, a sensor for measuring a blood sodium level of the patient, a sensor for measuring a blood chloride level of the patient, a sensor for measuring blood pH of the patient, a sensor for measuring blood partial O_2 pressure of the patient, a sensor for measuring blood partial CO_2 pressure of the patient, a sensor for measuring blood glucose level of the patient, a sensor for measuring blood triglyceride level of the patient, a sensor for measuring a central venous pressure of the patient, a sensor for measuring arterial blood pressure of the patient, a sensor for measuring urine production per time unit of the patient, a sensor for measuring a creatinine level of the patient, and a sensor for measuring body weight of the patient.

IN THE ABSTRACT:

On page 17, cancel lines 2-26 and substitute the following therefor:

--A device for administering a fluid to a patient by infusion and/or perfusion has one or more sensors for respectively measuring real-time values of one or more physiological parameters of a patient, a control unit connected to the sensors and being supplied with the measured real-time values, and a fluid administration device, connected to the control unit, which contains at least one solution to be administered to the patient by infusion and/or perfusion. The control unit is an expert system and processes the measured real-time values to obtain a processing result, and controls dispensing of the fluid by the fluid administration device dependent on the processing result.--.

REMARKS:

The present Amendment makes changes in the specification, drawing, claims and Abstract to conform to the requirements of United States patent practice. No new matter is added thereby.

The cancellation of claims 1-18 in favor of the claims submitted herein has been made solely because the amount of bracketing and underlining which would have been necessary to amend the original claims to conform to the requirements of 35 U.S.C. §112, second paragraph, would have been unduly burdensome and confusing. The currently submitted claims are intended to have the same scope as the cancelled claims, and accordingly no change in claim language is intended by the Applicants to be a surrender of any coverage within the scope of original claims 1-18.

Respectfully submitted,

Steven H. Noll (Reg. No. 28,982)

Steven H. Noll
Hill & Simpson
A Professional Corporation
85th Floor - Sears Tower
Chicago, Illinois 60606
(312) 876-0200 ext. 3899
Attorneys for Applicants.

BOX PCT

IN THE UNITED STATES DESIGNATED OFFICE
OF THE UNITED STATES PATENT AND TRADEMARK OFFICE
UNDER THE PATENT COOPERATION TREATY-CHAPTER II

REQUEST FOR APPROVAL OF DRAWING CHANGES

APPLICANTS: Abraham-Fuchs et al.
ATTORNEY DOCKET NO. P00,1120
INTERNATIONAL APPLICATION NO: PCT/DE98/03620
INTERNATIONAL FILING DATE: December 9, 1998
INVENTION: "DEVICE FOR GIVING A TRANSFUSION AND/OR PERFUSION TO A PATIENT"

Assistant Commissioner for Patents,

Washington, D.C.

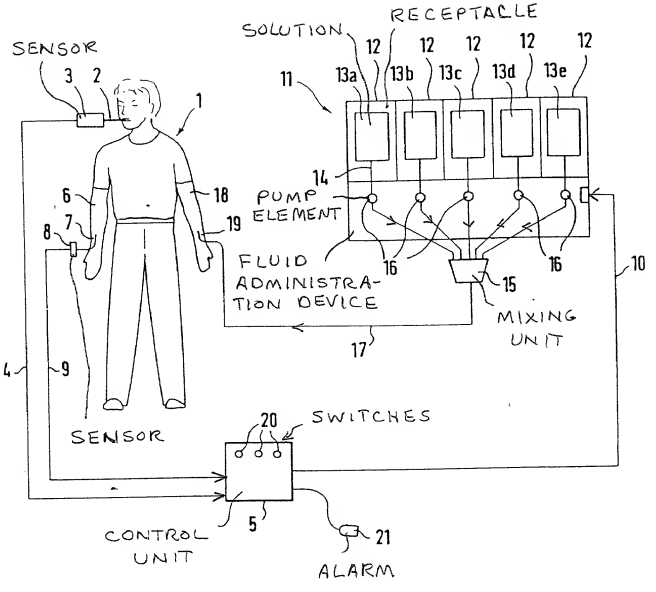
S I R:

Applicants herewith request approval of the drawing changes in the single figure, as shown on the attached drawing sheet marked in red.

Submitted by,

Steven H. Noll (Reg. No. 28,982)

HILL & SIMPSON
A Professional Corporation
85th Floor - Sears Tower
Chicago, Illinois 60606
Telephone: 312/876-0200 - Ext. 3899
Attorneys for Applicants.


SENSOR
3
2
1
SOLUTION
RECEPTACLE
12
12
12
12
12
11
13a
13b
13c
13d
13e
14
PUMP ELEMENT
6
7
8
18
19
FLUID ADMINISTRATION DEVICE
16
16
15
10
MIXING UNIT
17
4
9
SENSOR
20
SWITCHES
CONTROL UNIT
5
21
ALARM

IN THE UNITED STATES DESIGNATED OFFICE

OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

UNDER THE PATENT COOPERATION TREATY-CHAPTER II

AMENDMENT "A" PRIOR TO ACTION

APPLICANTS:	Abraham-Fuchs et al.
ATTORNEY DOCKET NO.	P00,1120
INTERNATIONAL APPLICATION NO:	PCT/DE98/03620
INTERNATIONAL FILING DATE:	December 9, 1998
INVENTION:	"DEVICE FOR GIVING A TRANSFUSION AND/OR PERFUSION TO A PATIENT"

Assistant Commissioner for Patents

Washington, D.C. 20231

Sir:

Applicants herewith amend the above-referenced PCT application as follows, and request entry of the Amendment prior to examination in the United States National Examination Phase.

IN THE TITLE:

Please cancel the present title and substitute the following title therefor:

--DEVICE FOR ADMINISTERING A FLUID TO A PATIENT BY INFUSION AND/OR PERFUSION--.

IN THE SPECIFICATION:

On page 1, cancel the material above line 6 and substitute the following therefor:

--TITLE

"DEVICE FOR ADMINISTERING A FLUID TO A PATIENT BY INFUSION AND/OR PERFUSION"

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention is directed to a device for administering a fluid to a patient, such as by infusion and/or perfusion.

DEVICE FOR GIVING AN INFUSION AND/OR PERFUSION TO A PATIENT

The invention relates to a device for giving an infusion and/or perfusion to a patient.

Main tasks of the intensive medicine are to balance disorders of the fluid-, electrolyte- and energy metabolism of a patient and to parenterally nourish the patient for a specific time. This is normally achieved by means of a mixture of various infusion solutions, which are given to the patient via a central-venous access. The composition of the infusion solutions is determined by the need of the patient and the underlying disorders of the cited metabolisms that must be balanced. These disorders can be roughly divided into a hyperhydration or a hypohydration, into disorders of the blood salt composition and into disorders of the energy metabolism, whereby these disorders occasionally influence each other and exhibit complex relations. Therefore, the planning of an infusion treatment requires the calculation of an individual infusion plan.

The water need is thereby determined via measurable losses and estimations appertaining non-measurable losses on the basis of rules of thumb. Disorders of the water metabolism are estimated by means of measurements of the body weight, by means of measuring the central venous pressure, by judging the circulation, as well as edemae or skin creases and finally by means of determining the losses (urine, breathing, sweat, bowel movement). The same parameters control the water balancing. The infusion amount to be supplied per clock unit is subsequently determined on the basis of this roughly estimated water need. The electrolytic need is also determined on the basis of rules of thumb via estimated losses and via electrolyte determinations in body fluids (serum, urine, fluids from drainages). Disorders of the blood salt composition are evaluated via laboratory examinations, whereby the

sodium-, potassium- and chloride levels in the blood are particularly relevant here, as much as other electrolytes as well. Finally, the caloric need as well is also mostly estimated via rules of thumb, which consider the body weight of the patient, the temperature and the disease of the patient. The caloric need can also be determined by indirect calorimetering. The caloric need is also divided via rules of thumb with respect to the nutrients protein, carbohydrates and fat, which form the caloric carriers to be supplied. The control of the parenteral nourishment, therefore ultimately the infusion result, ensues via the measurement of the blood sugar and/or the blood fat values. An individual infusion plan is calculated for each patient from the cited rough estimates, which plan is then realized by means of mixing together infusion solutions with salts. Then, these solutions are supplied with an infusion speed that is also prescribed by hand. The therapy, namely the infusion result, is subsequently checked by laboratory controls and is potentially modified.

The above specification shows that an infusion therapy - as it is currently carried out - contains many insecure factors, nutriments [sic] and assumptions that do not enable an infusion therapy that is adapted to the actual requirements. In particular, it is only possible to continuously monitor the therapy results, namely the effect of the infusion or, respectively, perfusion on the metabolism or, respectively, parameter to be balanced, in large time intervals, so that the entire infusion therapy or, respectively, perfusion therapy is extremely inflexible.

DE-AS 28 49 367 describes a device for purposes of regulating the glucose concentration in the blood stream of a person, whereby an infusion device is initiated to supply insulin to the blood stream in an amount that is determined on the basis of a mathematical equation.

DE 39 02 497 A1 also describes a perfusion device in the form of a heart supporting device, whereby the perfusion process is monitored on the basis of a firmly prescribed model.

Therefore, the invention is based on the object of proposing a device that allows an improved infusion therapy and/or perfusion therapy and that allows work largely adapted to actual conditions.

EP 0 702 966 A2 describes a dosing system for a contrast medium that is required in connection with medical imaging methods, whereby the concentration of the contrast medium and the injection parameters are patient-specifically adjusted in order to reduce the consumption of contrast medium and to increase the quality of the images.

US 4 392 849 relates to a control for an infusion pump with a closed loop. WO 86/02625 describes a system for purposes of mixing solutions for purposes of artificially nourishing, which system is controlled by means of a computer.

For purposes of solving this problem, a device for administering an infusion and/or perfusion to a patient is inventively provided, comprising:

- one or more sensor means for measuring real values of one or more patient-specific parameters,
- a control means that communicates with the one or more sensor means,
- an infusion device and/or perfusion device that communicates with the control means and that contains the infusion solution and/or perfusion solution to be given,

whereby the control means controls the infusion amount and/or perfusion amount that is to be supplied by means of the infusion device and/or perfusion device depending on the acquired real values.

The inventive device particulary advantageously represents a regulation system that makes it possible to supply infusion solution and/or perfusion solution, which supply is matched to the actually present conditions that can be determined by means of the real values. The one or more sensor means permanently communicate(s) with the control means, whereby the real values of the patient-specific parameter(s) is/are acquired essentially continuously or quasi continuously. Then, the control means controls the supply of the infusion solutions and/or perfusion solutions depending on the real values. As a result of the essentially continuous acquiring or quasi continuous acquiring of the real values, feedback is instantly received with respect to the success

of the supplied solutions, i.e whether the desired effect is achieved with regard to the metabolism to be balanced is recognized extremely fast.

As it has already been described, the metabolisms to be balanced or, respectively, the disorders to be controlled, however, partially represent extremely complex relations, not only with regard to the occurrence of the disorder but also with regard to its effect on the whole body. In view of these complex relations, which, however, are medically sufficiently determined, it is inventively provided that the control means conprises [sic] an expert system by means of which the incoming real values are processed, and whereby the controlling ensues based on it. These expert system [sic] is an intelligent regulation and control system, whereby the regulation and control mechanisms has [sic] been prepared based on physiological models and pathological models of the metabolism, therefore based on the medical findings about the complex relations. It is thus particularly advantageously possible to consider the described complex relations in the framework of the control and to enable an improved therapy. Another considerable advantage of the utilization of this expert system, which is certainly provided in the form of a corresponding regulation- and control software on the side of the control means, is that all known relations and information can be integrated into this expert system, which relations and information are required for purposes of determining the therapy and which are therefore required for the corresponding controlling, and which were previously introduced by the physician into the preparation of the therapy plan only on the basis of own knowledge, whereby a considerable error potential was certainly given hereby, which is eliminated with the arbitrarily expandable and structurable expert system. The previously cited problems no longer occur, since the inventive regulation, based on the real values processed in the control means that is fashioned as an expert system, allow [sic] a critically more precise infusion therapy or, respectively, perfusion therapy that can be replicated fast.

As it has already been described, particularly in the framework of the intensive medicine, it is necessary to control different metabolisms, so that different infusion solutions or perfusion solutions are to be supplied. In order to make allowance for this, it can be provided - in a way known per se from DE 28 55 713 C2 - that the infusion device and/or perfusion device contains a plurality of infusion solutions and/or perfusion solutions to be administered, whereby the control means controls the output of the individual required infusion amounts and/or perfusion amounts. Therefore, the device particularly advantageously makes it possible to utilize and administer the greatest variety of solutions, so that it can be used for a complete care. The infusion device and/ or perfusion device can thereby comprise a mixing device, in which the infusion solutions and/or perfusion solutions that are outputted upon control of the control means are mixed, i.e. that the mixing ensues in a controlled manner, the solution that is mixed together is subsequently supplied via a common line, so that a plurality of catheters do not have to be inserted. Advantageously, all steps always ensue upon control of the control means.

Therefore, physiological parameters or relations that are determined by the physician require to supply one or more infusion solutions or perfusion solutions in a deficient manner, balancing manner or excess manner. In order to fashion the device such that it can also be utilized for such cases, it can be provided, according to an advantageous further development of the inventive idea, that the control means comprises one or more selection means, via which the amount of one or more infusion solutions and/or perfusion solutions to be outputted can be adjusted at the user side for purposes of adjusting a deficient supply, balanced supply or excess supply. "Deficient supply, balancing supply and excess supply" means a corresponding supply of fluid with regard to the fluid or electrolyte metabolism, as much as a hypo-caloric supply, normo [sic]-caloric supply and hyper-caloric supply is possible in the case of influencing the caloric metabolism. Thereby, it has proven expedient when the control means itself is fashioned such that a deficient supply, balanced supply or excess supply is

automatically adjusted in order to be able to also take this decision away from the physician. The decision at the side of the control means regarding this ensues dependent on the expert system and the supplied real values or, respectively, ensues dependent on the corresponding parameter data.

In the case of a metabolism or a patient-specific parameter being able to be balanced by means of different infusion solutions and/or perfusion solutions, as this, for example, is valid for the caloric metabolism, whic [sic] can be influenced by means of adding fat solutions, protein solutions and/or carbohydrate solutions with respect to utilizing the respectively correct solution(s) or, respectively, the correct composition, it can be further provided that the control means has one or more sensor means, possibly further selection means for selecting the type of the infusion solutions and/or perfusion solutions to be supplied. Therefore, the physician can adjust the composition of the solution to be supplied with the aid of this selection means. For example, this can be such that he can select specific relations in terms of composition "fat/protein/carbohydrates", which are correspondingly considered in the framework of the output control. Here, the control means can also be fashioned for purposes of automatically selecting the type of the infusion solutions or perfusion solutions to be supplied.

Further, it has proven to be advantageous, with respect to a smooth and continuous utilization of the device, when one or more sensor means can be rinsed and calibrated by means of a calibrating solution provided in the infusion device and/or perfusion device, so that the one or more sensor means can always measure and supply correct real values. The rinsing and calibration, which can be controllable by means of the control means, can ensue several times in fixed time intervals and merely requires the utilization of a calibrating solution in the microliter range, so that the calibrating solution that is potentially introduced into the patient after the rinsing can, by no means, influence the therapy. Finally, it has proven expedient when an alarm device

is provided that can be operated by means of the control means depending on at least one measured real value, which alarm device makes it possible to correspondingly alarm the staff in the case of a found complication, normally when a real value differs considerably from a set value deposited in the control means.

The device can be fashioned for purposes of influencing the glucose metabolism and/or potassium metabolism of a patient in an infusion-supported manner and/or perfusion-supported manner. Alternatively or in addition, the device can be fashioned for purposes of influencing the caloric metabolism of a patient in an infusion-supported manner and/or perfusion-supported manner, as well as the device, alternatively or in addition, can be fashioned for purposes of influencing the fluid metabolism and/or electrolyte metabolism of a patient in an infusion-supported manner and/or perfusion-supported manner. The device should be fashioned for purposes of influencing each of the cited metabolisms with regard to an optimally broad utilization spectrum of the inventive device, as it is particularly requested in the intensive medicine.

According to a version of the invention, further physical parameters and/or chemical parameters, in addition to the parameters (metabolisms) to be balanced or to be influenced, are are [sic] measured by means of the one or more sensor means and are processed by means of the control means, namely at least one part of the following parameters: patial [sic] pressure O_2 of the inspired air and expired air, partial pressure CO_2 of the expired air, room temperature, air pressure, temperature of the patient, potassium level, sodium level and chloride level in the blood, pH value of the blood, partial pressure O_2 and CO_2 in the blood, glucose level in the blood, triglyceride level in the blood, central venous pressure, arterial blood pressure, urine production per time unit, creatinine, body weight.

The infusion device and/or perfusion device can be characterized in that it is fashioned for purposes of accepting a plurality of infusion solution and/or perfusion solutions, which can be supplied via separate lines of a central output line, and in that one or more sensor means control elements and/or pumping elements that influence the solution flow and that can be controlled via a control means that can be connected or is connected via a communication connection to the device. Therefore, an arbitrary number of solutions, particularly standard solutions, can be introduced into the inventive device, for example, can be hang up, which can then be connected to corresponding separate lines. Subsequently, the outputted amounts are separately and individually controlled by means of the control elements and/or pumping elements, which can be allocated to each line or, respectively, to each infusion solution and/or perfusion solution. Further, a mixing device for purposes of mixing the different infusion solutions and/or perfusion solutions that are to be supplied via the common output line, whereby this mixing device can be fashioned as a common drop catcher, in which the individual infusion solutions and/or perfusion solutions to be supplied can be given drop-by-drop.

Further advantages, innovations and details of the invention derive from the exemplary embodiment described in the following and on the basis of the drawing.

In the form of a schematic sketch, the Figure shows an inventive device. A patient is shown, who is to be therapeutically treated by means of administering an infusion or perfusion. A sensor means 3 is provided at a tubus 2, which sensor means 3 serves the respiratory gas sensory mechanism. The partial pressures of the oxygen and the carbon dioxide in the expired air can be measured by means of the sensor means 3, as well as the partial pressure of the oxygen in the inspired air. The real values, which are essentially continuously measured or which are quasi continuously measured, are given to a control means 4 via a communication line 4. An arterial permanent catheter 7 or a venous permanent catheter 7, which is followed by one or more sensor means 8

for the blood sensory mechanism, is arranged at the arm 6 of the patient 1, which sensor means 8 are connected to the control means 5 via a communication line 9. For example, the potassium levels, sodium levels and chloride levels in the blood, the blood-pH [...] the oxygen partial pressure and the carbon dioxide partial pressure in the blood, potentially also the blood glucose levels and the triglyceride levels, can be measured by means of the one or more sensor means 8. The central venous pressure can also be measured therewith, and potentially the arterial blood pressure as well. Real values, which are given to the control means 5, are also continuously determined or quasi continuously determined here.

The Figure shows merely an exemplary embodiment. A limitation concerning the utilizable one or more sensor means and the parameters measurable therewith is hereby not given. Rather, arbitrary sensor means for purposes of measuring arbitrary parameter can be utilized, as long as these are required for the control. The one or more sensor means should require an optimally small specimen volume in order to keep the load of the patient as low as possible, concerning the required blood consumption for the sensory mechanism, for example. The overall size should also be optimally small, since there is mostly a lack of space in intensive care units. The price should be low particularly with respect to the blood contact, since it must be a disposable product. Finally, the longevity of the one or more sensor means, as far as possible, should correspond to the duration of the treatment, so that a continuous exchange is not necessary. Further, the one or more sensor means can be rinsable and calibrateable by means of a calibrating solution, whereby this can ensue such that is controlled via the control means.

The control means 5 has a communication connection with an infusion device 11 and/or perfusion device 11 via a communication line 10. The device 11 comprises a plurality of receptacles 12 for accepting different infusion solutions and/or perfusion solutions 13 a, b, c, d, e, whereby merely five receptacles are provided in the shown

example; however, an arbitrary number can be provided. The solutions 13 a-e are standard solutions. Each solution 13 a-e, via a line 14, is connected to a mixing device 15 in the form of a drop catcher. A control element and/or pumping element 16 is inserted into each line 14, whereby each control element and/or pumping element 16 is controlled via the control means 5 in its operation. This means that the amount of the respective solution 13 a-e to be outputted can be controlled hereover. Since the real values are known to the control means 5 due to the sensory mechanism, it can thus be promptly reacted to corresponding changes, and the amount of the respective solution to be added can be varied by means of driving the respective control element and/or pumping element.

Each outputted solution is added drop-by-drop via the corresponding line 14 of the mixing device 15, where the individual solutions are mixed with one another. The solution, whose composition is matched to the actual real conditions, is given to the patient via the line 17 at the arm 18 via a corresponding catheter 19.

As it has already been described, the device 11 is entirely controlled via the control means 5. For this purpose, the control means 5 that is fashioned as a control computer is provided with an expert system in the form of a regulating and control software. The expert system has been configured on the basis of physiological metabolism models and pathophysiological metabolism models and serves the purpose of processing the supplied real values in order to generate the corresponding control plan therefrom.

As it has already been described, the utilizable sensor means are not limited. For example, the entire device can be fashioned as a glucose and potassium system. In these [sic] case, the potassium level and the glucose level in the blood is determined by means of a corresponding sensor means and, by means of the regulation of the device 11, which contains at least a glucose solution and a potassium solution in this

case, is kept in a constant range, whereby an insulin perfusor can be additionally utilized.

Alternatively (or in addition), the device can also be controlled dependent on the caloric need. In these [sic] case, the current caloric consumption of the patient (calories/minute) is determined via the method the [sic] indirect calorimetry. In this case, the device 11 contains (possibly in addition) electrolyte solutions, carbohydrate solutions, amino acid solutions and fat emulsions, as well as ready-to-use mixtures therefrom can be utilized. In addition, an insulin perfusor can also be provided here. An adequate amount of calories is supplied to the patient by the corresponding controlling/regulating via the control means 5. Hereby, it can be chosen between a hypocaloric nourishment, a normo-caloric nourishment and a hyper-caloric nourishment, whereby, appropriately, corresponding selection- and control means 5 (shown in the Figure by means of the switches 20) can be provided for this purpose. It can also be determined, via the respective determined caloric consumption, how much the patient burns, namely whether he preferably burns fat or carbohydrates, so that the composition can be correspondingly adjusted. However, the selection can also ensue automatically controlled by the control means. Further, only specific solutions to be administered or possibly specific mixture relations can be adjusted by means of the selection means 20. For reasons of safety, the blood glucose level, the potassium level, as well as the sodium level and the central venous pressure can be additionally measured. A volume overloading of the patient can be detected by means of determining the central venous pressure and the urine production.

Finally, the device can also be fashioned for purposes of regulating the water- and electrolyte metabolism. The amount of water needed by the patient is calculated by means of the control means 5 via the body weight, the temperature, the losses (drainages, urine, bowel movement) and the central venous pressure. The physician can also select here - by means of the selection means 20, for example - whether a

deficit, an exact balance or an excess of volume is to be achieved, including the desired degree. Appropriate one or more sensor means determine, in the blood, the electrolytes, sodium, potassium etc. [sic]. The amount and the composition of the infusion solution regarding its salt content are [sic] then calculated by means of the control means. In addition, the kidney function can also be determined by the creatinin level.

Finally, an alarm device 21 is provided by means of which an alarm can be given in the case of a complication.

Patent claims

1. Device for administering an infusion and/or perfusion to a patient, comprising:

- one or more sensor means (3, 8) for purposes of measuring real values of one or more patient-specific parameters,
- a control means (5) that communicates with the one or more sensor means (3, 8),
- an infusion device and/or perfusion device (11), which communicates with the control means (5) and which contains the infusion solution and/or perfusion solution to be administered,
- whereby the control means (11) controls the infusion amount and/or perfusion amount to be supplied by means of the infusion device and/or perfusion device (11) dependent on the acquired real values, and
- whereby the control means (5) comprises an expert system by means of which the incoming real values are processed and on the basis of which the control is carried out.

2. Device according to claim 1, whereby the infusion device and/or perfusion device (11) contains a plurality of infusion solutions and/or perfusion solutions (13a, b, c, d, e) to be administered, whereby the control means controls the output of the individual required infusion amounts and/or perfusion amounts.

3. Device according to claim 2, whereby the infusion device and/or perfusion device (11) comprises a mixing device (15), in which the infusion solutions and/or perfusion solutions (13a, b, c, d, e) outputted via the control means in a controlled manner are mixed.

4. Device according to one of the previous claims, whereby the control means (5) comprises one or more selection means (20), via which the amount of one or more

infusion solutions or perfusion solutions (13a, b, c, d, e) to be outputted can be adjusted at the user side for purposes of adjusting a deficient supply, balanced supply or excess supply.

5. Device according to one of the claims 1 through 3, whereby the control means (5) is fashioned for purposes of automatically adjusting a deficient supply, balanced supply or excess supply.

6. Device according to one of the previous claims, whereby the control means (5) comprises one or ore selection means (20), potentially further selection means (20), for purposes of selecting the type of the infusion solutions and/or perfusion solutions (13a, b, c, d, e) to be supplied.

7. Device according to one of the claims 1 through 5, whereby the control means (5) is fashioned for purposes of automatically selecting the type of the infusion solutions and/or perfusion solutions (13a, b, c, d, e) to be supplied.

8. Device according to one of the previous claims, whereby one or more sensor means (3, 8) can be rinsed and calibrated by means of a calibrating solution provided in the infusion device and/or perfusion device (11).

9. Device according to claim 8, whereby the rinsing and calibrating can be controlled by means of the control means (5).

10. Device according to one of the previous claims, whereby an alarm device (21) is provided, which can be operated by means of the control means (5) depending on at least one measured real value.

11. Device according to one of the previous claims, which device is fashioned for purposes of influencing the glucose metabolism and/or potassium metabolism of a patient in an infusion-supported manner and/or perfusion-supported manner.

12. Device according to one of the previous claims, which device is fashioned for purposes of influencing the caloric metabolism of a patient in an infusion-supported manner and/or perfusion-supported manner.

13. Device according to one of the previous claims, which device is fashioned for purposes of influencing the fluid metabolism and/or electrolyte metabolism of a patient in an infusion-supported manner and/or perfusion-supported manner.

14. Device according to one of the claims 1 through 13, whose infusion device and/or perfusion device is fashioned for purposes of accepting a plurality of infusion solutions and/or perfusion solutions (13a, b, c, d, e), which can be supplied via separate lines (14) of a central output line (17), whereby one or more control elements and/or pumping elements (16) that influence the solution flow are provided, which can be controlled via a control means (5) that can be connected or is connected to the device (11) via a communication connection.

15. Device according to claim 14, whose infusion device and/or perfusion device has a separate control element and/or pumping element (16) allocated to each line (14) or, respectively, to each infusion solution and/or perfusion solution (13a, b, c, d, e).

16. Device according to claim 14 or 15, whose infusion device and/or perfusion device comprises a mixing device (17) for purposes of mixing the different infusion solutions and/or perfusion solutions (13a, b, c, d, e) to be supplied via the common output line.

17. Device according to claim 16, whose mixing device (17) is fashioned as a common drop catcher, in which the individual infusion solutions and/or perfusion solutions (13a, b, c, d, e) to be supplied can be given drop-by-drop.

18. Device according to one of the claims 1 through 17, whereby at least one part of the following parameters are measured by means of the one or more sensor means (3, 8) and is processed by means of the control means (11):
Partial pressure O_2 in the inspired air and expired air, partial pressure CO_2 of the expired air, room temperature, air pressure, temperature of the patient, potassium level, sodium level, chloride level in the blood, pH-value of the blood, partial pressure O_2 and CO_2 in the blood, glucose level in the blood, triglyceride level in the blood, central venous pressure, arterial blood pressure, urine production per time unit, creatinin level, body weight.

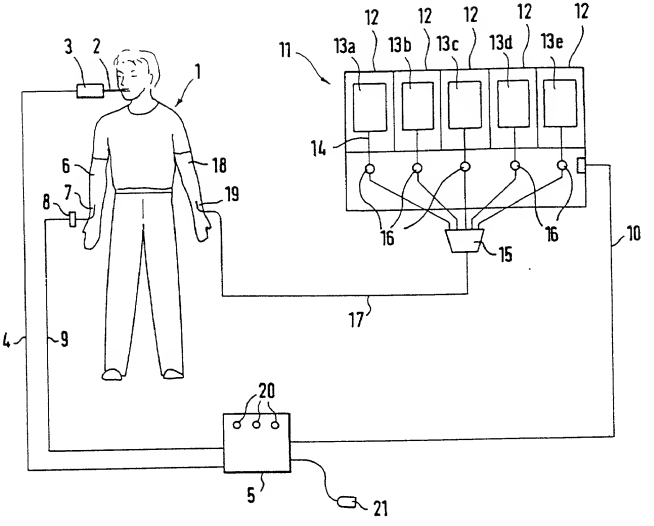
Abstract

Device for administering an infusion and/or perfusion to a patient

The invention relates to a device for purposes of administering an infusion and/or perfusion to a patient, comprising:

- one or more sensor means (3, 8) for purposes of measuring real values of one or more patient-specific parameters,
- a control means (5) that communicates with the one or more sensor means (3, 8),
- an infusion device and/or perfusion device (11), which communicates with the control means (5) and which contains the infusion solution and/or perfusion solution to be administered,
- whereby the control means (11) controls the infusion amount and/or perfusion amount to be supplied by means of the infusion device and/or perfusion device (11) dependent on the acquired real values, and
- whereby the control means (5) comprises an expert system by means of which the incoming real values are processed and on the basis of which the control is carried out.

Figure 1



COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY
(Includes Reference to PCT International Applications)

ATTORNEY'S DOCKET NUMBER **P00,1120**

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,
I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

"DEVICE FOR ADMINISTERING A FLUID TO A PATIENT BY INFUSION AND/OR PERFUSION"

the specification of which (check only one item below):

□ is attached hereto.

■ was filed as United States application
Serial No. **09/581,587**

on **June 15, 2000**,

and was amended

on **June 15, 2000** (if applicable).

□ was filed as PCT international application

Number _____

on _____,

and was amended under PCT Article 19

on _____ (if applicable).

I hereby state that I have reviewed and understand the contest of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

PRIOR FOREIGN/PCT APPLICATION(S) AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. 119:

COUNTRY (if PCT indicate "PCT")	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 35 USC 119
Germany	197 56 872.6	19.12.97	■ YES □ NO
			□ YES □ NO
			□ YES □ NO
			□ YES □ NO
			□ YES □ NO

Combined Declaration For Patent Application and Power of Attorney (Continued)
(Includes Reference to PCT International Applications)

ATTORNEY'S DOCKET NO.
P00,1120

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject mater of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, Untied States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application:

PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS DESIGNATING THE U.S. FOR BENEFIT UNDER 35 U.S.C. 120:

U.S. APPLICATIONS		STATUS (Check one)		
U.S. APPLICATION NUMBER	U.S. FILING DATE	PATENTED	PENDING	ABANDONED

PCT APPLICATIONS DESIGNATING THE U.S.					
PCT APPLICATION NO	PCT FILING DATE	U.S. SERIAL NUMBERS ASSIGNED (if any)			

POWER OF ATTORNEY: And I hereby appoint Messrs. John D. Simpson (Registration No. 19,842), Dennis A. Gross (24,410), Robert M. Barrett, (30,142) Steven H. Noll (28,982), Kevin W. Guynn (29,927), Robert M. Ward (26,517), Brett A. Valiquet (27,841), Edward A. Lehman (22,312), David R. Metzger (32,919), Todd Parkhurst (26,494) James D. Hobart (24,149), Melvin A. Robinson (31,870), Joseph P. Reagen (35,332), Michael R. Hull (35,902), Michael S. Leonard (37,557) William E. Vaughn (39,056) and Lewis T. Steadman (17,074), all members of the firm of Hill & Simpson, A Professional Corporation

Send Correspondence to:
HILL & SIMPSON
A Professional Corporation
85th Floor Sears Tower, Chicago, Illinois 60606

Direct Telephone Calls to:
312/876-0200
Ext. 3899

1.	FULL NAME OF INVENTOR	FAMILY NAME **ABRAHAM-FUCHS**	FIRST GIVEN NAME **KLAUS**	SECOND GIVEN NAME
2 0 1	RESIDENCE & CITIZENSHIP	CITY Erlangen	STATE OR FOREIGN COUNTRY Germany	COUNTRY OF CITIZENSHIP Germany
	POST OFFICE ADDRESS	POST OFFICE ADDRESS Graslitzer Str. 17	CITY Erlangen	STATE & ZIP CODE/COUNTRY D91058 Erlangen Germany
2.	FULL NAME OF INVENTOR	FAMILY NAME **BIRKHÖLZER**	FIRST GIVEN NAME **THOMAS**	SECOND GIVEN NAME
2 0 2	RESIDENCE & CITIZENSHIP	CITY Weisendorf	STATE OR FOREIGN COUNTRY Germany	COUNTRY OF CITIZENSHIP Germany
	POST OFFICE ADDRESS	POST OFFICE ADDRESS Sauerheimer Weg 9 c	CITY Weisendorf	STATE & ZIP CODE/COUNTRY D-91085 Weisendorf, Germany
3.	FULL NAME OF INVENTOR	FAMILY NAME **SCHMIDT**	FIRST GIVEN NAME **VOLKER**	SECOND GIVEN NAME
2 0 3	RESIDENCE & CITIZENSHIP	CITY Erlangen	STATE OR FOREIGN COUNTRY Germany	COUNTRY OF CITIZENSHIP Germany
	POST OFFICE ADDRESS	POST OFFICE ADDRESS Welsweg 3	CITY Erlangen	STATE & ZIP CODE/COUNTRY D-91054 Erlangen, Germany

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

SIGNATURE OF INVENTOR 201	SIGNATURE OF INVENTOR 202	SIGNATURE OF INVENTOR 203
DATE 7/27/00	DATE 7/26/00	DATE 16 & 2000 8/16/00

IN THE UNITED STATES DESIGNATED OFFICE
OF THE UNITED STATES PATENT AND TRADEMARK OFFICE
UNDER THE PATENT COOPERATION TREATY-CHAPTER II

CHANGE OF ADDRESS OF APPLICANTS' REPRESENTATIVE

APPLICANTS:	Abraham-Fuchs et al.
SERIAL NO.:	09/581,587
FILED:	June 15, 2000
TITLE:	"DEVICE FOR ADMINISTERING A FLUID TO A PATIENT BY INFUSION AND/OR PERFUSION"

Assistant Commissioner for Patents,
Washington, D.C. 20231

S I R:

Members of the firm of Hill & Simpson designated on the original Power of Attorney have merged into the firm of Schiff, Hardin & Waite. All future correspondence for the above-referenced application therefore should be sent to the following address:

SCHIFF, HARDIN & WAITE
Patent Department
6600 Sears Tower
Chicago, Illinois 60606

Submitted by,

Steven H. Noll (Reg. 28,982)

SCHIFF, HARDIN & WAITE
Patent Department
6600 Sears Tower
Chicago, Illinois 60606
Telephone: (312) 258-5790
Attorneys for Applicants.

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on September 7, 2000.

Steven H. Noll

STEVEN H. NOLL